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The Honorable Leonard P. Stark
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *Takeda Pharmaceutical Company Limited, et al. v. Teva Pharmaceuticals USA, Inc.*; C.A. No. 16-246-LPS

Dear Judge Stark:

We, along with Hogan Lovells, represent Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") in this matter. Pursuant to the Court's Order (D.I. 47), we write in response to Defendant Teva Pharmaceuticals USA, Inc.'s ("Teva") January 24, 2016 letter (D.I. 50). Despite only recently producing samples of its ANDA Product for testing, Teva contends that Takeda should be required to supplement its Preliminary Infringement Contentions now, prior to Takeda completing testing of Teva's product. For the reasons below, Teva's premature request should be denied.

I. Teva Only Recently Produced the Samples of its ANDA Product Necessary for Takeda to Fully Investigate its Infringement Claims

In accordance with the Court's September 19, 2016 Scheduling Order (D.I. 18) and Paragraph 4(c) of the Delaware Default Standard for Discovery, Takeda served Teva with its Preliminary Infringement Contentions on October 7, 2016. At that time, the case was still in its very early stages. Although Takeda had received Teva's ANDA, Teva had yet to respond to Takeda's discovery requests or produce samples of its ANDA Product. Two weeks later, Teva demanded the "immediate dismissal" of Takeda's suit, contending that Takeda's Preliminary Infringement Contentions were "wholly without merit." *See* Teva's Ex. 2. Takeda responded on November 1, 2016, explaining that there was no basis for Teva's contention that Takeda was required to make a final infringement determination based solely on the minimal discovery provided to date, especially given Teva had yet to even produce samples of its ANDA product. *See* Teva's Ex. 3. Takeda pointed out that if Teva was truly desirous of an expeditious resolution, "it should respond to Takeda's production requests on an expedited basis and promptly produce samples of its ANDA product." *Id.*

Teva, however, did not take any steps to expedite discovery or seek an expeditious resolution of the case. Instead, Teva impeded Takeda's ability to investigate infringement by outright refusing to produce samples of the excipients used in Teva's ANDA Product and by attaching arbitrary pre-conditions to the production of its product samples. *See* Ex. A (Teva's

Responses to Takeda's First Set of Requests for Production), Response to RFP Nos. 17-19. Specifically, Teva made the production of its ANDA Products contingent on Plaintiffs providing "sufficient information as to any tests, test protocols, or analytical procedures they intend to run on such samples before they expire, and the procedures they intend to follow to maintain the integrity of the samples that may be provided to Plaintiffs." *Id.* at Response to RFP No. 19.

On November 18, 2016—four days after refusing to provide samples and without providing any further substantive discovery—Teva again complained about the sufficiency of Takeda's Preliminary Infringement Contentions and demanded that Takeda either dismiss the case or supplement its preliminary contentions. *See* Teva's Ex. 6 at 2. The parties met and conferred on November 28, 2016. Takeda reiterated that it required Teva's samples to fully investigate its infringement claims—including under the doctrine of equivalents—and that Takeda would not agree to supplement its contentions without having the opportunity to test Teva's samples. Takeda also explained that it was inappropriate for Teva to make production of its samples contingent on Takeda divulging the details of its infringement testing. Teva maintained its objection and refused to produce its samples. On December 1, 2016, Teva finally agreed to produce samples of its ANDA Product without the attached conditions, but stated that it nevertheless intended to seek relief from the Court. *See* Teva's Ex. 7 at 1. Teva produced its samples on December 6, 2016 (*see* Teva's Ex. 8), and sought judicial intervention about two weeks later on December 22, 2016.

II. Teva's Premature Request that Takeda be Ordered to Supplement its Infringement Contentions Prior to Completing Testing of Teva's ANDA Product Should be Denied

Teva's attempt to prematurely seek supplementation of Takeda's Preliminary Infringement Contentions prior to the completion of Takeda's testing of Teva's ANDA Product should be denied. Teva contends that "Takeda's position that it needs discovery to identify its infringement theory is backwards" and that Takeda "does not need discovery" to provide its contentions. D.I. 50 at 2. As a preliminary matter, Teva is incorrect that Takeda has not identified its infringement theory. The asserted claims of the patent-in-suit require "an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent." [redacted] Takeda cited and produced scientific literature in support of its position.[1]

Moreover, Teva's contention that discovery is unnecessary ignores that this is a Hatch-Waxman case. Unlike the products at issue in typical patent infringement cases, Teva's ANDA product is not publicly available. Indeed, all of the materials necessary for Takeda's infringement investigation are in Teva's sole possession. It is well within Takeda's rights to investigate its infringement claims based on further discovery and testing of Teva's product. *See,*

[1] Teva spends the first half of its letter arguing claim construction. Claim construction, however, is separately before this Court. Takeda will not burden the Court by addressing Teva's claim construction arguments here, but rather, respectfully refers the Court to the parties' claim construction papers filed on December 20, 2016.

e.g., *Celgene Corp. v. KV Pharmaceutical Co.*, C.A. No. 07-4819, 2008 WL 2856469, at *3 (D.N.J. July 22, 2008) ("Because the Act has made the act of submitting an ANDA itself an act of infringement, in a Hatch-Waxman ANDA case, the attorney can conduct a reasonable and competent inquiry into the act of infringement by investigating whether a relevant ANDA has been filed.").

Teva's contention that "Takeda has all the discovery it needs" is likewise baseless. D.I. 50 at 2. Teva argues that Takeda should be made to supplement its contentions now because Takeda has had Teva's ANDA since before it provided its preliminary contentions. Merely producing the ANDA, however, is insufficient. As the Federal Circuit has explained, infringement under the Hatch-Waxman Act "'requires an infringement inquiry focused on what is likely to be sold following FDA approval,' an inquiry that 'must be based on all of the relevant evidence *including* the ANDA.'" *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1344 (Fed. Cir. 2014) (citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). Indeed, "other evidence may directly contradict the clear representations of the ANDA and create a dispute of material fact regarding the identity of the compound that is likely to be sold following FDA approval." *Id.* Therefore, the Federal Circuit has held that "it is not unreasonable for a patent owner to allege infringement under section 271(e)(2)(A) if the patent owner has evidence that the as-marketed commercial ANDA Product will infringe, even though the hypothetical product specified in the ANDA could not infringe."[2] *Id.*

Finally, and in any event, Teva's request should be denied because it is unnecessary and will likely be moot in the near future. Contrary to Teva's assertion, Takeda has never outright refused to supplement its Preliminary Infringement Contentions. Takeda has no intention to "forgo supplementing its infringement contentions, and then spring upon Teva expert testimony based on the testing of Teva's products during expert discovery," as Teva contends. D.I. 50 at 3. Rather, Takeda merely sought justified discovery to allow it to fully investigate its infringement claims. As discussed above, however, Teva repeatedly refused to provide samples of its product, and finally did so only on December 6, 2016, two weeks before seeking judicial intervention. In the short time since receiving the samples, Takeda has been diligently working to evaluate and test Teva's product, despite the challenges presented by the recent holidays and the schedule of Takeda's expert. Takeda will supplement its Preliminary Infringement Contentions once its testing is completed.

Conclusion

For the reasons discussed above, Takeda respectfully requests that the Court deny Teva's request to order Takeda to supplement its Preliminary Infringement Contentions

[2] Teva complains that Takeda has not supplemented its contentions despite now being in possession of Teva's samples. But as discussed above, Teva produced its samples just last month on December 6, 2016, and sought relief from the Court a mere two weeks later.

Respectfully,

/s/ Maryellen Noreika

Maryellen Noreika (#3208)

MN/bac
Enclosure

cc: Clerk of Court (Via Hand Delivery; w/enclosure)
All Counsel of Record (Via Electronic Mail; w/enclosure)